Camtronics
MEDICAL SYSTEMS

5519

K955519

510(k) Summary

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Date prepared: November 22, 1995
Name of contact person: Robert Kriedermann
Device trade name: Analytical Review Station (ARS2, subject to change)
Common name: Digital Imaging Workstation
Classification name: Medical Image Picture Archiving and Communications Device
Predicate substantially equivalent devices: Camtronics Ltd. "Video Plus" (K941979), Camtronics Ltd. "Archium" (K934496)
Device description: Digital image recording and display system for use in cardiac catheterization, radiography/fluoroscopy, ultrasound, or other digital imaging modalities.

Intended use: This product is intended primarily for on-line or remote viewing of cardiac catheterization angiography studies communicated by network, or transported by CD-R interchage media. The CD-R media may also be used as a full resolution digital image archive of complete cath lab studies, to replace cine film. The ARS2 can optionally be used with other digital imaging modalities, such as R/F, nuclear and ultrasound. The ARS2 provides the capability to write and read CD-R optical discs which are produced in accordance with the ACC/NEMA DICOM standard.

Predicate device specifications comparison:

	Camtronics Analytical Review Station	**Camtronics Analytical Workstation K941979**
Image Storage and Display		
Gray scale resolution	8 bit, 256 levels	8 bit, 256 levels
Stored image matrix size	512 x 512, 1024 x 512, or 1024 x 1024	512 x 512, 1024 x 512, or 1024 x 1024
Displayed image matrix size	1024 x 1024	1024 x 1024
Display video output	1280 x 1024, 72 hz refresh, color or monochrome; progressive	1280 x 1024, 72 hz refresh, color, progressive
Screen size	16 in., 19 in., or 20 in.	16 in., 19 in., or 20 in.
Image formats	DICOM, Siemens, GE, Philips, Picker, others; 1, 4, or 16 on 1	Siemens, GE, Philips, Picker, others; 1, 4, or 16 on 1
Media	Hard disk, CD-R	Hard disk, CD-R
Compression	JPEG Processes 1 and 14, dual-track lossy or lossless	JPEG Process 14, lossless
Image Processing Functions	Edge enhancement Zoom Window and level adjustment Gamma correction Subtraction	Edge enhancement Zoom Window and level adjustment Gamma correction Subtraction
Quantitative Analysis		
Ventricular Analysis	Sheehan/Dodge centerline algorithm for regional wall motion analysis, and LV volume computation; others	Sheehan/Dodge centerline algorithm for regional wall motion analysis, and LV volume computation.
Arteriogram Analysis	Saunders Data Systems, others	Artrek by QCS, Inc.

Performance data: Not required for determination of substantial equivalence for this class of device.

Conclusions drawn from clinical and nonclinical test data: Not required for determination of substantial equivalence for this class of device.

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